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09/868,083	11/19/2001	Zvi Cabantchik	A34366 PCT USA	5772

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EXAMINER

VENCI, DAVID J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,083

Applicant(s)

CABANTCHIK ET AL.

Examiner

David J Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 11-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-10, in the reply filed on September 24, 2004, is acknowledged. Claims 11-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Information Disclosure Statement

The information disclosure statement filed September 25, 2001, fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because an English translation of European Patent EP 0499712 has not been provided. In addition, the application serial number 09/868,155 typed at the top of PTO-1449 appears to be incorrect. It has been placed in the application file, but the information contained in European Patent EP 0499712 has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5-8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In step (c) of claim 1, the recitation of "a marker conjugated with a moiety that can be captured by the metal chelator" is indefinite because it is not clear whether "a marker" or "a moiety", or both, binds to the metal chelator. In addition, the recitation of "can be captured" is indefinite because it is unclear whether the method requires actual binding between a metal chelator and "a marker" and/or "a moiety."

In step (d) of claim 1, the recitations of "the amount" and "marker that has been released" lack antecedent bases because no prior step recites these limitation. Claim 1 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is the step of releasing marker. Step (b) recites the step of binding metal ion to the metal chelator. Following step (b), step (c) recites the

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step of binding a marker to the metal chelator. However, step (d) recites the step of determining the amount of released marker. It is unclear when, or by what mechanism, marker is released, or from where marker is released.

Step (d) is further indefinite because it is inconsistent with prior steps (b) and (c). Step (d) recites the step of determining the amount of marker released by capture of metal ions. Examiner interprets step (d) as indicating that marker is capture first, followed by capture of metal ions, which results in release of marker. However, this interpretation is inconsistent with steps (b) and (c) because the step of capturing metal ions (i.e. step b) occurs before the step of capturing marker (step c). Clarification is required.

In step (e) of claim 1, the recitations of "binding sites", "the concentration of binding sites", and "the metal ion bound to the marker" lack antecedent bases. In addition, the recitation of "after step b)" is indefinite because it is not clear at what point in the method "after step b)" refers. In addition, the recitation of "concentration of binding sites" is indefinite because it is not clear what physical parameters characterize "concentration of binding sites" or the required steps for determining "concentration of binding sites."

Step (e) is further indefinite because it is inconsistent with prior step (d). Step (d) recites the step of determining the amount of marker released by capture of metal ions. Examiner interprets step (d) as indicating competitive binding, where marker competes against metal ion for binding to chelator. However, step (e) recites "binding sites left available after step b)." It is not clear how marker is released in step (d) if binding sites are left available after step (b).

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In claim 3, the recitation of "desferrioxamine (DFO) polymer" is indefinite because it is not clear whether "desferrioxamine (DFO)" is a polymer-conjugated chelator by itself, or whether a separate polymer is conjugated to "desferrioxamine (DFO)."

In claims 5-8, the recitations of "marker is a fluorescent marker" or "marker is an antibody" or "marker is a chromogenic marker" or "marker is a calcein-iron complex" are indefinite because it is not clear how said markers can be "captured by the metal chelator" in step (c) of claim 1, or whether said markers are "conjugated with a moiety that can be captured by the metal chelator" as recited in step (c) of claim 1. It is also not clear how an antibody that binds to a metal-chelate complex can serve in a competitive assay of claim 1.

Claim 10 provides for the use of a polymer-conjugated form of a metal chelator, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-7 and 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Abuknesha (US 5,723,304).

Abuknesha teaches a method for determining the concentration of a non-bound metal ion (see col. 13, lines 27, "detection of metal complex or metal ions") in a sample of serum or other biological fluids (see col. 13, lines 51-54, "serum") comprising the steps of: providing a surface (see col. 9, line 30, "microtitre plates") coated with a polymer (see col. 9, lines 33-34, "soluble polymers attached to a suitable surface") that is conjugated to a metal chelator (see col. 13, line 16, "deferoxamine"), bringing said sample into contact with said coated surface (see col. 9, lines 39-40, "applying a sample to the carrier"), bringing into contact with said coated surface a marker conjugated with a moiety that can be captured by the metal chelator (see col. 14, lines 39-40, "first detectable species being linked to the antigenic species"), determining the amount of marker released by capture of metal ions (see col. 14, lines 52-61, "competitive immunoassay", "allowed to compete, with any entity to be detected"), and calculating the concentration of metal ion in the sample from the concentration of binding sites left available for capturing the metal ion bound to the marker (see col. 15, lines 29-36, "as the amount of entity to be detected increases, it occupies more antibody at the expense of the antigenic species linked to the first detectable species").

With respect to claim 2, Abuknesha teaches a method for determining the concentration of a non-bound metal ion wherein the metal ion is non-transferrin bound iron (see col. 13, lines 27, "detection of metal complex or metal ions") (see col. 13, line 20, "iron (Fe^{II} , Fe^{III})").

With respect to claim 3, Abuknesha teaches a method for determining the concentration of a non-bound metal ion wherein the polymer-conjugated form of a metal chelator is DFO (see col. 13, line 16, "deferoxamine").

With respect to claim 4, Abuknesha teaches a method for determining the concentration of a non-bound metal ion wherein the surface is a multiwell plate (see col. 9, line 30, "microtitre plates").

With respect to claim 5, Abuknesha teaches a method for determining the concentration of a non-bound metal ion wherein the marker is a fluorescent marker (see col. 9, line 57, "fluorophores").

With respect to claim 6, Abuknesha teaches a method for determining the concentration of a non-bound metal ion wherein the marker is an antibody that binds to DFO-Fe complex (see col. 13, lines 3-4, "the entity to be detected may be a species formed by interaction of an analyte species and a suitable agent") (see col. 13, lines 27, "detection of metal complex") (see col. 14, line 42, "antibody to the antigenic species").

With respect to claim 7, Abuknesha teaches a method for determining the concentration of a non-bound metal ion wherein the marker is a chromogenic marker (see col. 9, line 58, "chemiluminescent compounds").

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With respect to claim 9, Abuknesha teaches a method for determining the concentration of a non-bound metal ion wherein the metal ion is aluminum III (see col. 13, line 21, "aluminum (Al^{III})").

With respect to claim 10, Abuknesha teaches a method for determining the concentration of a non-bound metal ion wherein a sample of serum or other biological fluids is used (see col. 13, lines 51-54, "serum").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abuknesha (US 5,723,304) in view of Breuer et al. (268 AM. J. PHYSIOL. C1354 (1995)).

Abuknesha teaches a method for determining the concentration of a non-bound metal ion as substantially described supra.

Abuknesha does not teach a calcein-iron marker.

However, Breuer et al. teach the use of a calcein-iron marker for measuring intracellular iron concentrations (see Abstract). Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method of determining the concentration of a

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non-bound metal ion, as taught by Abuknesha, with the calcein-iron marker, as taught by Breuer et al., because Breuer et al. teach that Fe(II) caused 46% fluorescence quenching at a 4:1 iron:calcein ratio and “virtually complete” quenching at higher ratios (see p. C1356, col. 2). In addition, Breuer et al. teach that Fe(III) caused “very rapid and potent” quenching when FeCl₃ is dissolved in distilled water. A person of ordinary skill in the art may interpret these results as an indication that calcein is a favorable indicator of iron concentration and, thus, would serve well in an assay for iron in a sample of serum or other biological fluids.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

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10/18/07